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10/540,444	06/22/2005	Christelle Marie Guittet	05-530	1583
20306 7590 03/14/2008 MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606				
EXAMINER				
MACKOWEY, ANTHONY M				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,444

Applicant(s)

GUITTET ET AL.

Examiner

ANTHONY MACKOWEY

Art Unit

2624

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 9, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 7, 10, 12, 13, 15, 16 and 19-27 is/are rejected.
- 7) ☒ Claim(s) 2, 5, 11 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date 11/25/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Objections

Claims 3, 4, 6, 8, 10, 12, 13, 15, 17, 19, 21, 22, 24, 26 all recite ER and PR when referring to Oestrogen and Progesterone Receptors expression. While Examiner believes this notation to be known in the art and is clearly supported by the specification, for clarity, Examiner suggests clearly defining this notation in at least the independent claims (3, 4, 8, 10, 12, 13, 17, 19, 21, 22 and 26) as was done in claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 15, 16, 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 15 and 24 recite "the step of scoring ER or PR provides a first contribution thereto." To what, is the scoring providing a first contribution to?

Claims 7, 16 and 25 depend from claims 6, 15 and 24.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

Claims 19-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 19-27 define a computer program embodying functional descriptive material. However, the claim does not define a "computer-readable medium or computer-readable memory" and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). The scope of the presently claimed invention encompasses products that are not necessarily computer readable, and thus NOT able to impart any functionality of the recited

program. The examiner would have suggested amending the claim(s) to embody the program on “computer-readable medium” or equivalent; assuming the specification did NOT define the computer readable medium as a “signal”, “carrier wave”, or “transmission medium” which are deemed non-statutory. However, the specification, at page 18, lines 25-26 defines or exemplifies the medium as encompassing statutory media such as a “memory”, “floppy”, “optical drive”, etc, as well as *non-statutory* subject mater such as an “electrical signal”. Because the full scope of a computer-readable medium as properly read in light of the disclosure appears to encompass non-statutory subject matter (i.e., because the specification defines/exemplifies a computer readable medium as a non-statutory signal, carrier waver, etc.) the claim as a whole would still be non-statutory. The examiner suggests amending the claim to *include* the disclosed tangible computer readable storage media, while at the same time *excluding* the intangible transitory media such as signals, carrier waves, etc. Any amendment to the claim should be commensurate with its corresponding disclosure.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 10, 12, 13, 15, 19, 21, 22, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0165263 to Hamer et al. (newly cited, hereafter referred to as “Hamer”).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Hamer discloses a method of scoring Oestrogen and Progesterone Receptors expression (ER and PR) from image data obtained from histological slides (Fig. 2; pages 1-2, paragraphs 5-33; page 5, paragraphs 146-148; page 6, paragraph 150), the method including determining the number of relatively dark image pixels compared to relatively bright image pixels and scoring ER or PR in accordance with the magnitude of the number of relatively dark pixels (pages 8-9, paragraph 196, 198-201, *the ratio of sufficiently brown pixels to the total number of pixels is determined and used to score ER and PR*).

Regarding claim 10, Hamer discloses a computer apparatus for scoring ER and PR from image data obtained from histological slides (page 1, paragraph 12; pages 4-5, paragraphs 114—25; page 5, paragraphs 146-148; page 6, paragraph 150), the apparatus being programmed to determine the number of relatively dark image pixels compared to relatively bright image pixels and to score ER or PR in accordance with the magnitude of the number of relatively dark pixels (pages 8-9, paragraph 196, 198-201, *the ratio of sufficiently brown pixels to the total number of*

pixels is determined and used to score ER and PR).

Regarding claim 19, Hamer discloses a computer program for scoring ER and PR from image data obtained from histological slides (pages 3-4, paragraphs 84-101; page 5, paragraphs 146-148; page 6, paragraph 150), the program including instructions for controlling computer apparatus to determine the number of relatively dark image pixels compared to relatively bright image pixels and scoring ER or PR in accordance with the magnitude of the number of relatively dark pixels (pages 8-9, paragraph 196, 198-201, *the ratio of sufficiently brown pixels to the total number of pixels is determined and used to score ER and PR*).

Regarding claim 3, Hamer discloses a method of scoring ER and PR from image data obtained from histological slides (Fig. 2; pages 1-2, paragraphs 5-33; page 5, paragraphs 146-148; page 6, paragraph 150), the method including the steps of:

- a) determining the number of pixels in an image having relatively dark intensities compared to other pixels in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels*),
- b) determining pixel number thresholds to quantify scoring (page 9, Table 5), and
- c) comparing the number of relatively dark pixels with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claim 12, Hamer discloses a computer apparatus for scoring ER and PR from image data obtained from histological slides (page 1, paragraph 12; pages 4-5, paragraphs 114—25; page 5, paragraphs 146-148; page 6, paragraph 150), the apparatus being programmed to:

- a) determine the number of pixels in an image having relatively dark intensities compared to other pixels in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels*),
- b) determine pixel number thresholds to quantify scoring (page 9, Table 5), and
- c) compare the number of relatively dark pixels with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claim 21, Hamer discloses a computer program for scoring ER and PR from image data obtained from histological slides (pages 3-4, paragraphs 84-101; page 5, paragraphs 146-148; page 6, paragraph 150), the program including instructions for controlling computer apparatus to:

- a) determine the number of pixels in an image having relatively dark intensities compared to other pixels in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels*),
- b) determine pixel number thresholds to quantify scoring (page 9, Table 5), and
- c) compare the number of relatively dark pixels with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claim 4, Hamer discloses a method of scoring ER and PR from image data obtained from histological slides (Fig. 2; pages 1-2, paragraphs 5-33; page 5, paragraphs 146-148; page 6, paragraph 150), the method including the steps of:

a) determining what proportion of total blob area is brown blob area in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels and determining ratio of sufficiently brown pixels to total pixels*),

b) determining brown blob area proportion thresholds to quantify scoring (page 9, Table 5), and

c) comparing the brown blob area proportion with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claim 13, Hamer discloses a computer apparatus for scoring ER and PR from image data obtained from histological slides (page 1, paragraph 12; pages 4-5, paragraphs 114—25; page 5, paragraphs 146-148; page 6, paragraph 150), the apparatus being programmed to:

a) determine what proportion of total blob area is brown blob area in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels and determining ratio of sufficiently brown pixels to total pixels*),

b) determine brown blob area proportion thresholds to quantify scoring (page 9, Table 5), and

c) compare the brown blob area proportion with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claim 22, Hamer discloses a computer program for scoring ER and PR from image data obtained from histological slides (pages 3-4, paragraphs 84-101; page 5, paragraphs

146-148; page 6, paragraph 150), the program including instructions for controlling computer apparatus to:

a) determine what proportion of total blob area is brown blob area in an image (pages 8-9, paragraphs 196-198, *counting sufficiently brown pixels and determining ratio of sufficiently brown pixels to total pixels*),

b) determine brown blob area proportion thresholds to quantify scoring (page 9, Table 5), and

c) compare the brown blob area proportion with the thresholds and scoring ER or PR in accordance therewith (pages 8-9, paragraph 198-199).

Regarding claims 6, 15 and 24, Hamer further discloses scoring ER or PR provides a first contribution thereto (page 9, paragraph 199, *one of the two scores added together for the final score*) and includes:

a) providing a second contribution to scoring ER or PR by determining the number of relatively dark image pixels compared to relatively bright image pixels and deriving the second contribution in accordance with the magnitude of the number of relatively dark pixels (page 8, paragraph 197-199, *average saturation is determined, divided by the number of sufficiently brown pixels and scored*), and

b) combining the first and second contributions (page 9, paragraph 199, *the two scores are added together*).

Allowable Subject Matter

Claims 8, 9, 17 and 18 are allowed.

Claims 2, 5, 11 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7 and 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Claims 2, 7, 11 and 16 recite, “transforming the image data to a different image space having an intensity image plane and counting the number of pixels having intensities below a predetermined intensity threshold.” Hamer performs a color space transformation (pages 7-8, paragraphs 185-194) but only utilizes the Hue and Saturation planes in scoring ER and PR (hue threshold, saturation threshold, counting pixels with sufficiently large enough value of saturation) and even suggests the V component be ignored and not even be calculated (page 14, paragraph 261).

Claims 5, 8, 14 and 17 recite, “a) remapping pixel intensities in the image data to increase the contrast of relatively darker image regions and to transform relatively brighter image regions into a contrast-free background, b) converting the remapped image data into thresholded binary

images from which total blob area and brown blob area are discernible respectively, and c) expressing brown blob area as a proportion of total blob area.” As indicated above, Hamer does not utilize pixel intensity to score ER and PR and therefore does not disclose or suggest remapping pixel intensities.

Claims 9 and 18 depend from claims 8 and 17 respectively and therefore incorporate all the limitations of the claims from which they depend.

To modify the teachings of the Hamer reference to utilize pixel intensities would unnecessarily modify the primary function of the method, apparatus and program disclosed by Hamer as is clearly evident in Hamer’s emphasis of hue and saturation values and election to ignore the pixel intensity values.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20070053573 A1 to Rabinovich

US 6697509 B2 to De La Torre-Bueno

US 7272252 B2 to Del La Torre-Bueno

US 6416959 B1 to Giuliano et al.

US 20030096322 A1 to Giuliano et al.

US 6671624 B1 to Dunlay et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANTHONY MACKOWEY whose telephone number is (571)272-7425. The examiner can normally be reached on M-F 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AM
3/2/08

/Brian P. Werner/
Supervisory Patent Examiner, Art Unit 2624